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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
4010/367

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(Signature)

Application Number	Filed
09/749,980	12/27/2000

First Named Inventor
Elaine Lee

Art Unit	Examiner
3775	Michael J. Araj

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 42,059
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34.

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NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[x] *Total of 1 forms are submitted.

REASONS FOR REQUESTING PRE-APPEAL REVIEW

1) Status of Claims

Claims 1, 5-11, 14-16, 19, 22-24, 31, 32, and 34-37 are pending in the present application. Claims 5, 6, 22, 31, 32, and 34-37 were previously withdrawn pursuant to a restriction requirement. Thus, claims 1, 5-11, 14-16, 19, 22-24, 31, 32, and 34-37 are present for this Pre-Appeal Review.

2) Rejections under 35 U.S.C. 103(a)

The Examiner has withdrawn the prior art rejections under 35 U.S.C. 103(a) and applied new rejections under 35 U.S.C. 103(a), adding a newly cited reference, Soykan et al. (U.S. Patent No. 6,206,914) to each rejection.

Applicant respectfully states that the rejections are erroneous.

The newly cited art, Soykan et al. (U.S. Patent No. 6,206,914) ***teaches away*** from making the Examiner's purposed combination and further, modifying the compositions of the primary reference, Mariant et al., would ***render it unsatisfactory for its intended purpose***. Finally, one of skill in the art would have ***no motivation to combine*** Soykan et al. which teaches how to "prevent or limit thrombosis" with Mariant et al. to arrive at the claimed "vaso-occlusive composition."

A. Rejection over Mariant in view of Schwarz et al. and further in view of Soykan et al. under 35 U.S.C. §103(a)

Claims 1, 7-11, 19, and 23-24 are rejected under 35 U.S.C. §103(a) as being unpatentable in light of Mariant (U.S. Patent No. 5,624,461) in view of Schwarz et al. (U.S. Patent No. 4,414,976) and further in view of newly cited reference, Soykan et al. (U.S. Patent No. 6,206,914).

In response, Applicants respectfully traverse the rejection and its accompanying remarks. As amended previously, independent claim 1 is directed to the following:

> 1. A vaso-occlusive composition comprising a vaso-occlusive coil; and a bioactive material comprising a combination of two or more materials selected from the group consisting of (1) fibrin; (2) polyethylene glycol derivatives; (3) thrombin-coated gelatin granules; (4) balloons coated with iron microspheres; (5) trace metals, and (6) thrombus-stabilizing molecules

Previously, it was established that the invention of the claims is not taught or suggested by the combination of the primary reference, Mariant or the secondary reference, Schwarz et al. Mariant does not teach any bioactive material and moreover, does not teach any of the specific

materials listed in independent claim 1. Schwarz et al. teaches one of the claimed materials in that it teaches a "plasminogen-activator-inhibitor or plasmin-inhibitor, preferably aprotinin." (Schwarz et al., col. 1, lines 61-62). Schwarz et al. does not teach fibrin. It does not teach a polyethylene glycol derivative. It does not teach thrombin-coated gelatin granules. It does not teach balloons coated with iron microspheres. It does not teach trace metals. As for thrombus-stabilizing molecules, it teaches a "plasminogen-activator-inhibitor or plasmin-inhibitor" as alternatives. Schwarz et al. does not teach a ***combination*** of two or more of the Markush group elements as required by independent Claim 1.

To address this deficiency, the Examiner has now cited a new reference, Soykan et al. (U.S. Patent No. 6,206,914), for allegedly teaching "the use of fibrin to make the device in assisting treatment of aneurysms less prone to tearing." The Examiner argues that since Soykan et al. teaches "fibrin" and Schwarz et al. teaches a "thrombus-stabilizing molecule," Soykan et al. and Schwarz et al., in combination with Mariant et al. (which does not teach any bioactive material), teach ***two*** of the claimed Markush group elements as required by independent Claim 1.

Applicant states that one of skill in the art would simply not make such combination to arrive at the present invention since Soykan et al. teaches compositions to "limit thrombosis" (Soykan et al., col. 10, lines 60-67), which is not compatible with the present invention teaches "vaso-occlusive" compositions. Even if such combination were made, Applicant states that there is no evidence that the claimed vaso-occlusive composition would be the end result.

Applicant also respectfully states that the rejection fails because the new reference, Soykan et al., teaches away from using the claimed combination of fibrin and thrombus-stabilizing molecules. Applicant requests that the Examiner must consider all of the teachings of Soykan et al. and cannot simply pick and choose the disclosure of "fibrin."

Indeed, in reviewing the totality of the disclosures of the Soykan et al. reference, it is clear that Soykan et al. teaches fibrin but it certainly does ***not teach a thrombus-stabilizing molecule such as a plasminogen-activator-inhibitor***. Rather, it teaches a ***plasminogen activator***, not a ***plasminogen-activator-inhibitor***. As one of skill in the art would appreciate, a plasminogen activator is certainly not equivalent to a plasminogen-activator-inhibitor, as their names inherently imply. The fact that Soykan et al. teaches plasminogen activators is not surprising given that Soykan et al. teaches the importance of "limiting thrombosis" and teaches utilizing a "tissue plasminogen activator" to "prevent or limit thrombosis." (Soykan et al., col. 10, lines 65-67). Nowhere does

Soykan et al. teach a vaso-occlusive composition (as required by the preamble of pending independent claim 1) or any bioactive agents to promote occlusion or thrombosis.

As disclosed by Soykan et al., "polyurethane can be used to regulate degradation of the fibrin covering the stent and to slow release of the cellular products from the stent. Heparin, or other anticoagulants, such as polyethylene oxide, hirudin, and ***tissue plasminogen activator***, can be incorporated into the stent prior to implantation in an amount effective to prevent or limit thrombosis." (Soykan et al., col. 10, lines 60-67)(emphasis added).

Indeed, Applicant states that modifying the device of Mariant et al. (which teach no bioactive agents whatsoever) to add the plasminogen-activator-inhibitor of Schwarz et al. and the plasminogen activator and fibrin of Soykan et al. would result in an invention that is rendered unsatisfactory for its intended purpose. The modified device would contain both the plasminogen activator of Soykan et al. as well as the plasminogen-activator-inhibitor of Schwarz et al. The Examiner has not addressed whether such combination can function as a "vaso-occlusive composition" as required by the claims. Indeed, the Examiner asserts that "[i]t would have been obvious…to have created the combination of Mariant and Schwartz [sic] et al. with a fibrin coating in view of Soykan et al., in order to make a more robust device ***that can better function to treat an aneurysm***." (Office Action, page 3, first paragraph)(emphasis added). Applicant respectfully disagrees.

The purpose of the device of the primary reference, Mariant et al., which is to provide an improved device to treat an aneurysm, would certainly be thwarted and not met by modifying the device of Mariant et al. according to the Examiner to add the fibrin/tissue plasminogen activator components taught by Soykan et al. The law is clear that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The Examiner has failed to address how and why the proposed modification of Mariant et al. would still render it satisfactory for its intended purpose.

The only way for the combination of the Soykan et al., Mariant et al., and Schwarz et al. to arrive at the present invention would require one of skill in the art to discard the teachings of Soykan et al. that speaks to the importance of anti-coagulation and limiting thrombosis and pick and choose only the fibrin element taught in the compositions of Soykan et al. Applicant asserts that the Examiner cannot pick and choose certain portions of a reference to the exclusion of other relevant portions. "A prior art reference must be considered in its ***entirety***, i.e., as a whole, ***including***

portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.,* 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469, U.S. 851 (1984)(emphasis added). The fact that Soykan et al. ***teaches away from vaso-occlusive compositions and teaches away from a thrombosis-stabilizing molecule such as a plasminogen-activator-inhibitor*** must be considered.

B. Rejection over Mariant in view of Schwarz et al., in view of Soykan et al. and further in view of Eder et al. under 35 U.S.C. §103(a)

Claims 14-15 are rejected under 35 U.S.C. §103(a) as being unpatentable in light of Mariant (U.S. Patent No. 5,624,461) in view of Schwarz et al. (U.S. Patent No. 4,414,976), in view of Soykan et al. (U.S. Patent No. 6,206,914) and further in view of Eder et al. (U.S. Pat. No. 5,980,550).

In response, Applicants respectfully traverse the rejection and its accompanying remarks, and further states that the rejection has been rendered moot by the amendment of rejected independent claim 1, upon which rejected claims 14 and 15 ultimately rely. The additional reference, Eder et al., also does not teach or suggest the missing claim feature. That is, it does not teach a bioactive material comprising a combination of two or more of the claimed materials. Rather, Eder et al. teaches "thrombolytics such as tissue plasminogen activator (TPA), streptokinase, urokinase, hirudin and growth factors…" (Eder et al., col. 6, lines 5-8), but none of the claimed materials.

C. Rejection over Mariant in view of Schwarz et al., in view of Soykan et al. and further in view of Nikolchev et al. under 35 U.S.C. §103(a)

Claim 16 is rejected under 35 U.S.C. §103(a) as being unpatentable in light of Mariant (U.S. Patent No. 5,624,461) in view of Schwarz et al. (U.S. Patent No. 4,414,976), in view of Soykan et al. (U.S. Patent No. 6,206,914) and further in view of Nikolchev et al. (U.S. Pat. No. 6,526,979).

In response, Applicants respectfully traverse the rejection and its accompanying remarks, and further states that the rejection has been rendered moot by the amendment of rejected independent claim 1, upon which rejected Claim 16 ultimately relies. The additional reference, Nikolchev et al., also does not teach or suggest the missing claim feature. That is, it does not teach a bioactive material or the claimed combination of two or more of the materials of claim 1.